

REMARKS

The amendments above and the remarks below are in response to a final Office Action mailed on September 17, 2009. In the final Office Action, Claims 1-5, 9-12, 15-16 and 19-20 were rejected under 35 U.S.C. 103(a) over U.S. Pats. Nos. 5,092,846 to Nishijima et al. ("Nishijima"); 5,149,330 to Brightbill ("Brightbill") and 5,156,596 to Balbierz et al. ("Balbierz"). Filed herewith also are a Request for Continued Examination ("RCE") to allow further consideration of the amendment claims after the final Office Action and an Information Disclosure Statement.

Independent Claims 1 and 15 have been amended to recite the catheter lumen being sealed by a catheter valve supported by the junction housing and the catheter lumen and side arm lumen both emptying into the access tube lumen when the catheter is coupled to the introducer using the multi-function adapter.

Nishijima

Nishijima discloses a catheter introducer that includes a body 2 defining an inner cavity 11 that is distal to a valve means 3, as shown in Figure 1B. A sheath tube 5 is connected to the body so that it communicates with the inner cavity. The body also includes a branching member 7 which is connected to a connecting tube 8 for the injection of heparin or saline into the inner cavity. A dilator 12 that is connected to a grip 13 can be inserted through the valve means for dilating openings. A catheter 4 can be inserted through the dilator, as shown in Figure 1A of Nishijima.

Nishijima, among other aspects, does not disclose a catheter that couples with an infusion introducer by passing through a hemostasis valve and into an access lumen, wherein the catheter includes its own catheter valve supported by a junction housing and is configured to seal access to the at least one lumen defined in the catheter tube. For at least these reasons, Nishijima alone also does not teach or suggest the presently claimed invention.

Balbierz

An insertion assembly 11 shown in Figure 1 of Balbierz includes a needle hub 12 supporting a needle 18. The needle hub fits within an outer cannula hub 22 and the needle extends through an outer cannula 28 supported by the cannula hub. The needle and outer cannula are inserted into a vein and the needle withdrawn, leaving only the outer cannula. Col. 7; ll. 14-21 of Balbierz. The outer cannula hub includes a valve means 70, as shown in Figures 3 and 4 of Balbierz. The valve means 70 includes a self sealing septum 72.

Balbierz also discloses a multi-lumen catheter assembly 10, as shown in Figure 5. The multi-lumen catheter assembly 10 includes a positioning assembly 38 with Luer locking mechanism 66 that attaches it to the insertion assembly, as shown in Figures 3 and 4 of Balbierz. The catheter includes an outer cannula 28 and an inner cannula 52 with a distal end portion 56 "that extends beyond the distal end portion 32 of the outer cannula 28." Col. 7; ll. 45-47 of Balbierz. The other end of the inner cannula is fed by a proximal access region 48, as shown in Figure 4 of Balbierz.

Notably, inner cannula 52 of Balbierz extends from the side arm of the Y-shape through and out of the outer cannula without fluid communication between the lumen of the inner cannula and the outer cannula. In contrast, the present invention in independent Claims 1 and 15 recites a side arm opening distal the hemostasis valve and a catheter lumen that both empty into an access tube lumen. In addition, neither the inner, nor outer, cannula of Balbierz has a catheter valve supported by a junction housing and configured to seal access to a catheter lumen, as recited in the presently claimed invention. For at least these reasons, Balbierz alone does not teach or suggest the present invention as recited in the claims.

Brightbill

Brightbill discloses a dual-lumen catheter tube 14 that inserts into a large-bore catheter tube 12. First and second lumens 16, 18 are defined in the catheter tube 14 and a portion of an outer wall 41 of the catheter tube 14 forms a third lumen 22 between it and an inner wall 42 of the catheter tube 12, as shown in Figure 3 of Brightbill. Catheter tubes 12, 14 are secured together after connection by a connector 31 that includes a first connector portion 35 on the proximal end of catheter 12 and second connector portion 36 on the distal end of catheter 14.

A manifold 44 is secured to the proximal end of the catheter tube 14 and provides attachment for extension tubing 46, 48 and 50, as shown in Figure 2B of Brightbill. Channels 54, 56, 58 connect the lumens 16, 18, 22 in fluid communication with the extension tubing 46, 48, 50. Brightbill describes that lumens 16, 18, 22 "are independent and non-communicative with one another, and various fluids simultaneously carried thereby do not mix prior to entering the blood stream." Col. 3; ll. 29-32.

In contrast, the present invention in independent Claims 1 and 15 recites a side arm opening distal the hemostasis valve and a catheter lumen that both empty into an access tube lumen and thus are "communicative" with each other. In addition, neither the first nor second tubes 12, 14 have a catheter valve supported by a junction housing and configured to seal access to the at least one lumen defined in the catheter tube, as recited in the presently claimed invention. For at least these reasons, Brightbill alone does not teach or suggest the present invention as recited in the claims.

Alleged Combination of Nishijima with Balbierz or Brightbill

One of ordinary skill in the art would not combine Balbierz and Nishijima. As noted above, there is no fluid communication between the lumen of the inner and outer cannulae in Balbierz. Balbierz stresses the importance of this design several times. "The distal end portion 56 of the inner cannula 52, in the embodiment illustrated, extends beyond the distal end portion 32 of the outer cannula 28. In this manner non-compatible medicaments can be introduced into a blood vessel or other body cavity a spaced distance apart from one another. Or, samples can be removed from a region of the vessel or cavity which is free of a particular medicament which is being introduced via another lumen." Col. 7; ll. 45-53 of Balbierz (emphasis added). Thus, the relationship of the inner and outer cannula of Balbierz is no motivation to combine the branching member 7 of Nishijima with Balbierz.

In fact, Balbierz, when differentiating the prior art, teaches against introduction of liquids immediately distal of a septum (which is analogous to a valve) because of undesirable stagnation.

Also, any liquids being flowed through the outer cannula lumen (i.e., through the annular space between the inner and outer cannulae) must be introduced downstream of the septum whereby the space immediately downstream of the

septum (and upstream of the introduction of the liquid) is substantially stagnant. Furthermore, the fact that this space is not flushed out means that if the fluid being flowed through the outer cannula lumen is changed, there will be a transition time during which a mixture of the old and new fluids will be present. As some medicaments are not compatible with others such mixing can be undesirable.

See, col. 2, ll. 1-12 of Balbierz.

Balbierz also stresses the importance of not introducing flow downstream of the valve. "It is also important to understand that flow from the second passage 42 into the outer cannula lumen 34 washes through and cleanses the valve means 70 thereby eliminating any dead space which would be present if the flow into the outer cannula lumen 34 was introduced downstream of the valve means 70."

One of ordinary skill in the art would also not combine Brightbill and Nishijima. Brightbill has a similar teaching to Balbierz (showing just how much the art views mixing and dead space as a problem to be avoided) by pointing out that the lumens 16, 18, 22 are "independent and noncommunicative with one another, and various fluids simultaneously carried thereby do not mix prior to entering the blood stream." Col. 3; ll. 29-32. Brightbill goes on to describe that each of the lumens terminate at positioned spaced apart from each other "thereby ensuring that fluids simultaneously carried within each of the lumens 16, 18, 22 do not mix prior to being assimilated into the bloodstream." Col. 3; ll. 32-37.

Nishijima teaches this same structure that Balbierz and Brightbill deplore, the end of the branching member opening into the cavity 11 of the main body 2 which communicates with sheath tube 5, as shown in Figure 1B. One of ordinary skill in the art, therefore, would not combine Nishijima with either Balbierz or Brightbill in a way that would teach or suggest a side arm opening distal the hemostasis valve and a catheter lumen that both empty into, and are in fluid communication with, an access tube lumen, as recited in independent Claims 1 and 15 of the present application.

Even if Nishijima were (erroneously) combined with either Balbierz and/or Brightbill, none of these references, or any of the other cited references, appears to teach or suggest both an introducer having a hemostasis valve and a side arm lumen extending into an access tube lumen distal the hemostasis valve, and a catheter with a catheter valve, wherein the catheter can be

coupled to a hub of the introducer such that the catheter tube passes through the hemostasis valve and into the access lumen, as recited in independent Claims 1 and 15. The remaining Claims 4-5, 9-12 and 16-20 depend from, and further patentably distinguish, Claims 1 and 15. The rejection under 35 U.S.C. 103(a) has therefore been overcome.

New Claim 27 has been added. The new claim recites an introducer with a hub, a side arm and a hemostasis valve, and a catheter that is coupled by an adapter to and which fits through the hemostasis valve and that includes a catheter valve supported by the junction housing. It is believed, based on the arguments above, that Claim 27 is also allowable over the cited references.

CONCLUSION

In view of the remarks and amendments presented above, it is respectfully submitted that the pending claims of the present invention are in condition for allowance. It is respectfully requested that a Notice of Allowance be issued in due course. The Examiner is requested to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is believed that a two-month extension of time is needed for this Response and charging of such fees to Deposit Account 50-1225 referencing Attorney Docket No. ECC-5062CIP2DV is hereby authorized. If any other appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge said fees, such as under 37 C.F.R. §§ 1.16 or 1.17, or to credit any overpayment, to Deposit Account 50-1225 referencing Attorney Docket No. ECC-5062CIP2DV.

Respectfully submitted,

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